IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF MISSISSIPPI NORTHERN DIVISION

AMANDA BOWEN PLAINTIFF

VS. CIVIL ACTION NO.: 3:13-cv-00601-DPJ-LRA

HAROLD JASON BLALOCK, M.D., MISSISSIPPI UROLOGY CLINIC, E.J. BLANCHARD, JR., M.D., MISSISSIPPI BAPTIST MEDICAL CENTER, INC., MISSISSIPPI BAPTIST HEALTH SYSTEMS, INC., MISSISSIPPI BAPTIST MEDICAL ENTERPRISES, INC., BOSTON SCIENTIFIC CORPORATION, JOHN DOES 1-25 AND JOHN DOE CORPORATIONS 2-50

DEFENDANTS

NOTICE OF 30(b)(6) DEPOSITION OF BOSTON SCIENTIFIC CORPORATION

TO: BOSTON SCIENTIFIC CORPORATION

c/o J. Carter Thompson, Jr., Esq.C. Mead Hartfield, Esq.Baker Donaldson, Bearman, Caldwell, and Berkowitz, PCP.O. Box 14167Jackson, MS 39236

PLEASE TAKE NOTICE that the Plaintiff will take the deposition upon oral examination of the corporate representative(s) of Defendant, pursuant to Federal Rule of Civil Procedure 30(b)(6) on September 1, 2015, to be taken at The Law offices of DLA Piper, located at 1251 6th Ave., 26th Floor, New York, NY 10020, beginning at 10:00 a.m. eastern time, before a court reporter or some other officer duly authorized to administer oaths. In accordance with Rule 30(b)(6), Defendant is requested to present one or more officers, officials, agents, or other persons as may be necessary who consent to testify on its behalf, concerning the following:

- 1. All matters related to the Interrogatories propounded to Boston Scientific Corporation.
- 2. All matters related to the Request for Production propounded to Boston Scientific Corporation.
- 3. The Boston Scientific products that are the subject of this case, namely: Boston Scientific 8FR Flexima Nephrostomy, Catalog No. 27-179, UPN M001271790; AND Boston Scientific 8FR Percuflex Stent, Catalog No. 24.549, Product No. M001245490.

- 4. All information related to the Class 2 Medical Device Recall that resulted in Boston Scientific initiating an "Urgent Medical Device Field Correction Notification" letter dated March 18, 2009 regarding the nephrostomy that is the subject of this litigation. *See* Exhibit "A."
- 5. All efforts that were taken by Boston Scientific to ensure Hospitals or other medical facilities received the "Urgent Medical Device Field Correction Notification" letter (**Exhibit "B"**), including efforts to obtain the referenced "Acknowledgement Forms."
- 6. The defect present in the Boston Scientific 8FR Flexima Nephrostomy, Catalog No. 27-179, UPN M001271790.
- 7. The "Urgent Medical Device Field Correction Notification" letter dated March 18, 2009. **Exhibit "B."**
- 8. Any and all communications between Boston Scientific and the FDA related to the Class 2 Medical Device Recall involving the Boston Scientific 8FR Flexima Nephrostomy, Catalog No. 27-179, UPN M001271790.
- 9. The process undertaken by Boston Scientific to inform hospitals or other medical facilities of the Class 2 Medical Device Recall involving the 8FR Flexima Nephrostomy, Catalog No. 27-179, UPN M001271790.
- 10. How Boston Scientific was made aware of the problem and/or defect with the 8FR Flexima Nephrostomy, Catalog No. 27-179, UPN M001271790, and the fact that during the attempted removal of the device sutures would separate from the catheter and remain in patients.
- 11. How many complaints/reports, and the substance thereof, Boston Scientific received regarding the Flexima Nephrostomy's that were the subject of the Class 2 Medical Device recall related to sutures separating from the catheter and remaining in patients during the attempted removal of the device **prior to** March 18, 2009.
- 12. How many complaints/reports, and the substance thereof, Boston Scientific received regarding the Flexima Nephrostomy's that were the subject of the Class 2 Medical Device recall related to sutures separating from the catheter and remaining in patients during the attempted removal of the device **after** March 18, 2009.
- 13. The number of "Urgent Medical Device Field Correction Notification" letters that Boston Scientific sent out in relation to the Class 2 Medical Device Recall involving the Boston Scientific 8FR Flexima Nephrostomy, Catalog No. 27-179, UPN M001271790.
- 14. The number of "Acknowledgement Forms" Boston Scientific received back in relation to the "Urgent Medical Device Field Correction Notification" letters sent out on March 18, 2009.
- 15. Any and all efforts taken by Boston Scientific related to hospitals or other medical facilities which did not sign and return the "Acknowledgement Form" that accompanied the "Urgent Medical Device Field Correction Notification" letter dated March 18, 2009.
- 16. A full description of the revised removal instructions provided to hospitals and other medical facilities related to the Class 2 Medical Device Recall involving the Boston Scientific 8FR Flexima Nephrostomy, Catalog No. 27-179, UPN M001271790, including the differences in the original removal instructions and the revised removal instructions.
- 17. A full description of what was expected of physicians or other medical providers in removal process of a Boston Scientific 8FR Flexima Nephrostomy, Catalog No. 27-179, UPN M001271790, under the revised removal instructions provided in the "Urgent Medical Device Field Correction Notification" letter dated March 18, 2009.

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- 18. A full description of what was expected of hospitals or other medical facilities related to the Boston Scientific 8FR Flexima Nephrostomy, Catalog No. 27-179, UPN M001271790, as a result of the "Urgent Medical Device Field Correction Notification" letter dated March 18, 2009.
- 19. Any and all actions taken by Boston Scientific to attempt to remedy the defect and/or problem with the Boston Scientific 8FR Flexima Nephrostomy, Catalog No. 27-179, UPN M001271790, to ensure that sutures would not separate from the catheter and remain in patients bodies during the attempted removal of the device.
- 20. A description of whether the Flexima Nephrostomy tubes that were the subject of the Class 2 Medical Device Recall are designed and/or manufactured differently now than they were prior to March 18, 2009.
- 21. A description of the design and manufacturing process for Boston Scientific 8FR Flexima Nephrostomy, Catalog No. 27-179, UPN M001271790.
- 22. Any design drawings, or the like, related to Boston Scientific 8FR Flexima Nephrostomy, Catalog No. 27-179, UPN M001271790.
- 23. The process by which Boston Scientific instructions for use and/or removal instructions and/or labels and/or warnings, are drafted, created and/or are assigned to medical devices, including the Boston Scientific 8FR Flexima Nephrostomy, Catalog No. 27-179, UPN M001271790.
- 24. Why during attempted removal of Boston Scientific 8FR Flexima Nephrostomy, Catalog No. 27-179, UPN M001271790 devices, the sutures were separating from the catheter and remaining in patient's bodies.
- 25. The process of instituting Boston Scientific medical device recalls including any and all interaction between Boston Scientific and the FDA.

Pursuant to Rule 30(b)(6), the designee or designees for Defendant under 30(b)(6) are also requested to produce the following documents at the deposition:

1. All documents requested of this Defendant by Plaintiff in discovery.

Please take further notice that the deposition will be continued until completed and will be taken pursuant to the Federal Rules of Civil Procedure for all such uses provided for in the Rules unless stipulated otherwise.

You are hereby notified to appear and to take such part in said depositions, as you deem proper.

RESPECTFULLY SUBMITTED, this the <u>31ST</u> day of August, 2015.

PLAINTIFF, AMANDA BOWEN

BY: /s/ R. Paul Williams, III
R. PAUL WILLIAMS, III

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CERTIFICATE OF SERVICE

I, do hereby certify that I have this day filed, a true and correct copy of the *above* and foregoing using the Federal Electronic Filing System (pacer) which sent a correct copy of the forgoing document to:

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THIS, the 31ST day of August, 2015.

/s/ *R. Paul Williams, III* R. PAUL WILLIAMS, III